AMENDMENTS TO THE CLAIMS

1-28. Canceled

29. (Currently amended) A method for assigning [[an]] a human individual having breast cancer to one of a plurality of categories in a clinical trial, comprising:

(a) classifying said individual as ER^-[[,]] and *BRCA1*; ER^-[[,]] and sporadic; ER+[[,]] and ER/AGE high; ER+, ER/AGE low[[,]] and LN+; or ER+, ER/AGE low[[,]] and LN^-[[,]]; wherein ER+ designates a high ER level and ER^- designates a low ER level, wherein said ER/AGE is a metric of said ER level relative to the age of said individual, and wherein LN+ designates a greater than 0 lymph nodes status in said individual and LN^- designates a 0 lymph nodes status in said individual;

(b) determining for said individual a profile comprising measurements of the levels of expression of at least two respective genes for which markers are listed in

(b1) Table 1 if said individual is classified as ER^-[[,]] and sporadic;

(b2) Table 2 if said individual is classified as ER^-[[,]] and *BRCA1*;

(b3) Table 3 if said individual is classified as ER+[[,]] and ER/AGE high;

(b4) Table 4 if said individual is classified as ER+, ER/AGE low [[,]] and LN+; or

(b5) Table 5 if said individual is classified as ER+, ER/AGE low [[,]] and LN^-;

(c) classifying, on a computer, said individual as having a good prognosis or a poor prognosis by a method comprising comparing said profile to a good prognosis template and/or a poor prognosis template, wherein:

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS PLLC
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

(i) said individual is classified as having a good prognosis if said profile has a high similarity to said good prognosis template, has a low similarity to said poor prognosis template, or has a higher similarity to said good prognosis template than to said poor prognosis template, wherein said profile has a high similarity to said good prognosis template if the similarity to said good prognosis template is above a predetermined threshold, or has a low similarity to said poor prognosis template if the similarity to said poor prognosis template is below said predetermined threshold, or

(ii) said individual is classified as having a poor prognosis if said profile has a high similarity to said poor prognosis template, has a low similarity to said good prognosis template, or has a higher similarity to said poor prognosis template than to said good prognosis template, wherein said profile has a high similarity to said poor prognosis template if the similarity to said poor prognosis template is above said predetermined threshold, or has a low similarity to said good prognosis template if the similarity to said good prognosis template is below said predetermined threshold,

wherein said good prognosis template comprises measurements of the average levels of expression of said at least two respective genes ~~that are representative of levels of expression of said at least two respective genes~~ in a plurality of good outcome patients, and said poor prognosis template comprises measurements of the average levels of expression of said at least two respective genes ~~that are representative of levels of expression of said at least two respective genes~~ in a plurality of poor outcome patients, and wherein a good outcome patient is a breast cancer patient who has non-reoccurrence of metastases within a first period of time after initial diagnosis and a poor outcome patient is a patient who has reoccurrence of metastases within a second period of time after initial diagnosis; and

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS PLLC
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

(d) assigning said individual to one category in a clinical trial if said individual is classified as having a good prognosis, and assigning said individual to a second category in said clinical trial if said individual is classified as having a poor prognosis.

30–41. (Canceled)

42. (Currently amended) A method for predicting a human breast cancer patient as having a good prognosis or a poor prognosis, comprising:

(a) classifying said breast cancer patient into one of the following classes: (a1) ER$^-$[[,]] and sporadic; (a2) ER$^-$[[,]] and *BRCA1*; (a3) ER+[[,]] and ER/AGE high; (a4) ER+, ER/AGE low[[,]] and LN+; or (a5) ER+, ER/AGE low[[,]] and LN$^-$;

(b) determining a profile comprising measurements of levels of transcripts of, or proteins encoded by, respective genes in a plurality of genes in a cell sample taken from said breast cancer patient, said respective genes comprising at least two of the genes for which markers are listed in

(b1) Table 1 if said breast cancer patient is classified as ER$^-$[[,]] and sporadic;

(b2) Table 2 if said breast cancer patient is classified as ER$^-$[[,]] and *BRCA1*;

(b3) Table 3 if said breast cancer patient is classified as ER+[[,]] and ER/AGE high;

(b4) Table 4 if said breast cancer patient is classified as ER+, ER/AGE low [[,]] and LN+; or

(b5) Table 5 if said breast cancer patient is classified as ER+, ER/AGE low[[,]] and LN$^-$; and

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS^{PLLC}
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

(c) comparing, on a computer, said profile to a good prognosis template and/or a poor prognosis template, wherein said good prognosis template comprises measurements of average levels of transcripts of, or proteins encoded by, said respective genes ~~in said plurality of genes that are representative of levels of transcripts of, or proteins encoded by, said respective genes~~ in a plurality of good outcome patients, and said poor prognosis template comprises measurements of average levels of transcripts of, or proteins encoded by, said respective genes ~~in said plurality of genes that are representative of levels of transcripts of, or proteins encoded by, said respective genes~~ in a plurality of poor outcome patients, and wherein a good outcome patient is a breast cancer patient who has non-reoccurrence of metastases within a first period of time after initial diagnosis and a poor outcome patient is a patient who has reoccurrence of metastases within a second period of time after initial diagnosis; and

(d) classifying said breast cancer patient (i) as having a good prognosis if said profile has a high similarity to said good prognosis template, has a low similarity to said poor prognosis template, or has a higher similarity to said good prognosis template than to said poor prognosis template, wherein said profile has a high similarity to said good prognosis template if the similarity to said good prognosis template is above a predetermined threshold, or has a low similarity to said poor prognosis template if the similarity to said poor prognosis template is below said predetermined threshold, or (ii) as having a poor prognosis if said profile has a high similarity to said good prognosis template, has a low similarity to said poor prognosis template, or has a higher similarity to said good prognosis template than to said poor prognosis template, wherein said profile has a high similarity to said poor prognosis template if the similarity to said poor prognosis template is above said predetermined threshold, or has a low similarity to said good prognosis template if the similarity to said good prognosis template is below said predetermined threshold,

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS^{PLLC}
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

wherein ER^+ designates a high ER level and ER^- designates a low ER level, wherein said ER/AGE is a metric of said ER level relative to the age of said patient, and wherein LN^+ designates a greater than 0 lymph nodes status in said patient and LN^- designates a 0 lymph nodes status in said patient.

43-53. (Canceled)

54. (Previously presented) The method of claim 42, wherein said ER/AGE is classified as high if said ER level is greater than $c \cdot (AGE - d)$, and wherein said ER/AGE is classified as low if said ER level is equal to or less than $c \cdot (AGE - d)$, wherein c is a coefficient, AGE is the age of said patient, and d is an age threshold.

55-57. (Canceled)

58. (Currently amended) The method of claim 42, wherein said individual is ER^-[[,]] and sporadic, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 1.

59. (Currently amended) The method of claim 42, wherein said individual is ER^-[[,]] and sporadic, and said plurality of genes comprises all of the genes for which markers are listed in Table 1.

60. (Currently amended) The method of claim 42, wherein said individual is ER^-[[,]] and *BRCA1*, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 2.

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS PLLC
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

61. (Currently amended) The method of claim 42, wherein said individual is ER⁻[[,]] and *BRCA1*, and said plurality of genes comprises all of the genes for which markers are listed in Table 2

62. (Currently amended) The method of claim 42, wherein said individual is ER+[[,]] and ER/AGE high, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 3.

63. (Currently amended) The method of claim 42, wherein said individual is ER+[[,]] and ER/AGE high, and said plurality of genes comprises all of the genes for which markers are listed in Table 3.

64. (Currently amended) The method of claim 42, wherein said individual is ER+, ER/AGE low [[,]] and LN+, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 4.

65. (Currently amended) The method of claim 42, wherein said individual is ER+, ER/AGE low [[,]] and LN+, and said plurality of genes comprises all of the genes for which markers are listed in Table 4.

66. (Currently amended) The method of claim 42, wherein said individual is ER+, ER/AGE low[[,]] and LN⁻, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 5.

67. (Currently amended) The method of claim 42, wherein said individual is ER+, ER/AGE low[[,]] and LN⁻, and said plurality of genes comprises all of the genes for which markers are listed in Table 5.

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS PLLC
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

68-88. (Canceled)

89. (Currently amended) A computer-implemented method for predicting a human breast cancer patient as having a good prognosis or a poor prognosis, comprising:

classifying, on a computer, said patient as having a good prognosis or a poor prognosis based on a profile comprising measurements of levels of transcripts of, or proteins encoded by, respective genes in a plurality of genes in a cell sample taken from said patient, said plurality of genes comprising at least two of the genes for which markers are listed in

(b1) Table 1 if said breast cancer patient is classified as ER^-[[,]] and sporadic;

(b2) Table 2 if said breast cancer patient is classified as ER^-[[,]] and *BRCA1*;

(b3) Table 3 if said breast cancer patient is classified as ER+[[,]] and ER/AGE high;

(b4) Table 4 if said breast cancer patient is classified as ER+, ER/AGE low[[,]] and LN+; or

(b5) Table 5 if said breast cancer patient is classified as ER+, ER/AGE low[[,]] and LN^-,

wherein ER^+ designates a high ER level and ER^- designates a low ER level, wherein said ER/AGE is a metric of said ER level relative to the age of said patient, wherein LN^+ designates a greater than 0 lymph nodes status in said patient and LN^- designates a 0 lymph nodes status in patient,

wherein said classifying is carried out by a method comprising comparing said profile to a good prognosis template and/or a poor prognosis template, wherein said good prognosis template comprises measurements of average levels of transcripts of, or proteins encoded by, said respective genes ~~in said plurality of genes that are representative of levels of transcripts of, or proteins encoded by, said respective genes~~ in a plurality of good outcome patients, and said

poor prognosis template comprises measurements of average levels of transcripts of, or proteins encoded by, said respective genes ~~in said plurality of genes that are representative of levels of transcripts of, or proteins encoded by, said respective genes~~ in a plurality of poor outcome patients, and wherein a good outcome patient is a breast cancer patient who has nonreoccurrence of metastases within a first period of time after initial diagnosis and a poor outcome patient is a breast cancer patient who has reoccurrence of metastases within a second period of time after initial diagnosis, and wherein:

(i) said individual is classified as having a good prognosis if said profile has a high similarity to said good prognosis template, has a low similarity to said poor prognosis template, or has a higher similarity to said good prognosis template than to said poor prognosis template, wherein said profile has a high similarity to said good prognosis template if the similarity to said good prognosis template is above a predetermined threshold, or has a low similarity to said poor prognosis template if the similarity to said poor prognosis template is below said predetermined threshold, or

(ii) said individual is classified as having a poor prognosis if said profile has a high similarity to said poor prognosis template, has a low similarity to said good prognosis template, or has a higher similarity to said poor prognosis template than to said good prognosis template, wherein said profile has a high similarity to said poor prognosis template if the similarity to said poor prognosis template is above said predetermined threshold, or has a low similarity to said good prognosis template if the similarity to said good prognosis template is below said predetermined threshold.

90. (Previously presented) A method for assigning a breast cancer patient to one of a plurality of categories in a clinical trial, comprising:

(a) determining if said person has a good prognosis or a poor prognosis using the method of claim 89; and

(b) assigning said patient to one category in a clinical trial if said patient is determined to have a good prognosis, and a different category if that patient is determined to have a poor prognosis.

91-93. (Canceled)

94. (Previously presented) The method of claim 89, wherein said ER/AGE is classified as high if said ER level is greater than $c\cdot(\text{AGE} - d)$, and wherein said ER/AGE is classified as low if said ER level is equal to or less than $c\cdot(\text{AGE} - d)$, wherein c is a coefficient, AGE is the age of said patient, and d is an age threshold.

95. (Currently amended) The method of claim 89, wherein said individual has been classified as ER-[[,]] and sporadic, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 1.

96. (Currently amended) The method of claim 89, wherein said individual has been classified as ER-[[,]] and sporadic, and said plurality of genes comprises all of the genes for which markers are listed in Table 1.

97. (Currently amended) The method of claim 89, wherein said individual has been classified as ER-[[,]] and *BRCA1*, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 2.

98. (Currently amended) The method of claim 89, wherein said individual has been classified as ER-[[,]] and *BRCA1*, and said plurality of genes comprises all of the genes for which markers are listed in Table 2.

99. (Currently amended) The method of claim 89, wherein said individual has been classified as ER+[[,]] and ER/AGE high, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 3.

100. (Currently amended) The method of claim 89, wherein said individual has been classified as ER+[[,]] and ER/AGE high, and said plurality of genes comprises all of the genes for which markers are listed in Table 3.

101. (Currently amended) The method of claim 89, wherein said individual has been classified as ER+, ER/AGE low[[,]] and LN+, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 4.

102. (Currently amended) The method of claim 89, wherein said individual has been classified as ER+, ER/AGE low[[,]] and LN+, and said plurality of genes comprises all of the genes for which markers are listed in Table 4.

103. (Currently amended) The method of claim 89, wherein said individual has been classified as ER+, ER/AGE low[[,]] and LN-, and said plurality of genes comprises at least two of the genes for which markers are listed in Table 5.

104. (Currently amended) The method of claim 89, wherein said individual has been classified as ER+, ER/AGE low[[,]] and LN-, and said plurality of genes comprises all of the genes for which markers are listed in Table 5.

LAW OFFICES OF
CHRISTENSEN O'CONNOR JOHNSON KINDNESS PLLC
1420 Fifth Avenue
Suite 2800
Seattle, Washington 98101
206.682.8100

105. (Previously presented) The method of claim 29, wherein said measurements of the levels of expression of said at least two respective genes in said good prognosis template is an average of expression levels of transcripts of said at least two respective genes in cell samples taken from said plurality of good outcome patients and wherein said measurements of the levels of expression of said at least two respective genes in said poor prognosis template is an average of expression levels of transcripts of said at least two respective genes in cell samples taken from said plurality of poor outcome patients.